

Appl. No. : 10/762,772
Filed : January 22, 2004

REMARKS

Please reconsider the above-captioned application in light of the above amendments and the following comments.

The Recited Structure Is Not Taught or Suggested by the Cited Art

The Examiner rejected Claims 1-11 under 35 U.S.C. § 102(b) and 103(a) as unpatentable over Applicant's previous U.S. Patent No. 5,839,437. Applicant has amended certain of the claims. Further, Applicant respectfully traverses the Examiner's characterization of the cited '437 patent, and contends that all of the pending claims currently are in condition for allowance.

'437 Device Structure

The '437 patent teaches a retainer ring anti-disconnect assembly 42 that cooperates with a specific type of endotracheal tube neck band 10 to secure an attachment to the tube. As disclosed, the *ring 44 is circular* and has connectors 48 attached to it. There is *no structure to define holds for the connectors 48*. In practice, the neck band 10 has a front surface 16 formed of "loops" adapted to retain the "hook" portion of hook-and-loop fastener (col. 3, ll. 14-16). Portions 20, 22 of the neck band 10 pass through slots 34 of the tube bracket 36 and connect back onto themselves via the hook-and-loop fastener. As such, the neck band 10 holds the tube bracket 36 in place.

Two of the ring connectors 48 have hook-type material, and thus can connect onto the neck band 10 via the hook-and-loop fastener. In practice, the ring 44 is fit over the tube 38 and the connectors 48 engage the neck band 10 via hook-and-loop fastener to hold the ring in place.

The arrangement of the '437 patent is very helpful and important in the industry. However, it has some serious limitations. For example, the *ring 44 can only be used with certain compatible neck bands 10*. As such, *many commercially-available neck bands are incompatible with the ring 44*, and thus the ring cannot be used with these products. Further, it is desirable to enhance the fit of the device so that the ring fits securely in place on the tracheostomy tube.

Claim 1

Claim 1 has been amended, and now recites, *inter alia*, a ring having a pair of opposed extensions defining primary strap holds, and further having a pair of secondary strap holds, and a void within the ring configured to allow passage of a tracheostomy tube through the ring, the ring extensions extending away from the void. As discussed above, the '437 patent teaches a circular

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ring that has no such extensions. Such extensions are not taught or suggested by the '437 patent. Accordingly, Applicant respectfully requests that the rejection of this claim, and Claims 2-6 which depend therefrom, be removed.

Claims 4-5

Claims 4 and 5 depend from Claim 1. The Examiner contends that the '437 patent teaches the ring being secured to the tracheostomy collar by the neck strap (See Office Action p. 3). The Examiner further clarified her position as: "inasmuch as the neck strap is hook and looped with the ring strap hold the examiner is reading this as meeting the functional limitations of the claim." (See Office Action p. 4). Applicant respectfully contends that this is an incorrect interpretation of the '437 teachings, and even still does not teach the limitations of Claims 4-5. Figures 3-5 and the text of the '437 patent clearly show that the ring 44 has ring connectors 48. The ring 44 is secured to the neck band 10 via the ring connectors 48, which attach to the front surface 16 of the neck band 10 by hook-and-loop fasteners (col. 3, ll. 43-48). *The neck band 10 does not attach to the ring 44.*

Claims 4 and 5 each have been amended to increase their clarity. The '437 patent does not teach or suggest all the limitations of these claims as amended. For example, the '437 patent *does not teach the neck strap 10 in any way engaging any part of the ring.*

Claim 6

Claim 6 depends from Claim 1, and additionally recites that the ring has a major axis extending between the primary strap holds and a minor axis extending between the secondary strap holds, and the major axis is greater than the minor axis. The Examiner rejected Claim 6, contending that this limitation is a "mere matter of design consideration", and is not patentably distinct over the '437 patent. Applicant respectfully disagrees with the Examiner's contention, and submits that the recited aspect is a substantial improvement that provides important advantages. Clearly, this structure was not taught or suggested by the '437 patent.

A rejection of claims as being merely a "design choice" is not appropriate when the claimed structure or arrangement solves a particular problem that has not been contemplated or addressed by the prior art. An example of this rule is found in In re Chu, 36 U.S.P.Q. 2d 1089, 1095 (Fed. Cir. 1995), in which a "design choice" rejection was reversed. The Chu Court held that 1) there was no teaching or suggestion in the prior art to modify the prior art structure to

resemble the claimed structure, and 2) there was evidence of that Applicant's claimed structure solved problems associated with the prior art.

The structure set out in Claim 6, in which the major axis (between the primary holds) is greater than the minor axis, solves particular problems that the inventor encountered with the '437 device, and takes advantage of other aspects not contemplated by the '437 patent. Discussion of some of the advantages follows.

As discussed above, the ring 44 of the '437 patent can only be used with specifically compatible neck bands 10. Many commercially used tracheostomy collars do not contemplate using a ring 44, and are incompatible with such a ring. Applicant's claimed device resolves this problem by reciting structure that enables a user to use the same neck strap that holds the tracheostomy tube to also secure the ring. As such, the connectors 48 of the '437 patent, which were incompatible with many tracheostomy collar neck straps, are no longer needed; *the compatibility problem is now resolved* because the existing neck strap of any tracheostomy collar can also be used to retain the recited ring.

As stated in paragraph [0027] of Applicant's specification, "a significant advantage of described embodiments is that the retainer 60 can be added and removed from a commercially available assembly quickly and easily and without requiring the addition or removal of additional components." The ring 44 of the '437 patent cannot accommodate the neck band 10; the ring 44 is circular and includes no extensions to define strap holds. The '437 patent does not contemplate engaging the ring 44 with the neck band 10, and does not teach or suggest any structure to allow such engagement.

Another advantage to the structure of Claim 6 is that the primary strap holds will more closely align with strap holds formed in the tracheostomy flange. Thus, it will be possible to direct the neck strap of a tracheostomy collar through both the flange holds and ring primary holds. This was not possible with the '437 device.

A still further advantage of the Claim 6 invention is that the ring can be more easily and effectively secured in place. As specifically discussed in paragraphs [0033] – [0036] of Applicant's specification, the arrangement of the strap holds 74, 76 spaced relatively far apart influences the direction of force vectors acting on the ring, and as the spacing between the primary holds is increased, the holding force urging the ring against the flange is also increased.

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Notwithstanding the advantages of spacing the primary strap holds far apart, the specification also clarifies that limiting the height h of the ring will avoid interference with patient movement. (See specification, paragraph [0037]). The recited arrangement, with the major axis being greater than the minor axis, enables a ring to take advantage of the benefits of a far-apart spacing of the primary strap holds while still limiting the height h of the ring, and thus not interfere with patient movement or comfort.

Applicant submits that the arrangement recited in Claim 6 solves specific problems with the '437 device, and takes advantage of aspects never contemplated in the '437 patent to enhance the ease of use and better secure the ring in place on the tube. The recited arrangement is certainly not a mere design choice relative to the '437 device. Applicant thus respectfully requests that the Examiner withdraw her rejection.

Method Claims Recite Patentable Method

Independent method Claim 8 has been amended to better clarify the interaction of the method steps with the recited structure. As discussed above, the '437 device employs connectors 48 that are permanently attached to a circular ring 44. In use, the ring 44 is slipped over a tube, and the connectors 48 are attached to the neck band 10 by hook-and-loop fasteners. As also discussed above, this procedure is only possible with neck bands that are specifically compatible with the ring connectors 48.

The '437 patent does not teach or suggest all of the limitations of Claim 8. For example, Claim 8 recites, *inter alia*, securing a tracheostomy collar neck strap to flanged tracheostomy tube neck strap holds and simultaneously to retainer primary strap holds. At least this limitation is not taught or suggested by the '437 patent, which requires a neck band 10 and two separate connectors 48 to hold the ring 44 in place.

Applicants respectfully request that the Examiner withdraw the rejection of Claim 8, and Claims 9-10 which depend therefrom.

New Claims

New Claims 12-20 have been added to more fully recite subject matter that Applicant considers to be part of the invention. New Claim 12 is an independent claim from which new Claims 13-20 depend. All of the new claims are currently in condition for allowance.

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Conclusion

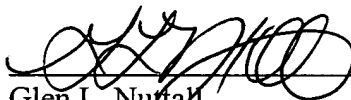
For the foregoing reasons, it is respectfully submitted that the rejections and objections set forth in the outstanding Office Action are inapplicable to the present claims and specification. Accordingly, early issuance of a Notice of Allowance is most earnestly solicited.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Respectfully submitted,

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